NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, et al., Plaintiffs, v. MSN LABORATORIES PRIVATE LTD. et al., Defendants.	**Civil Action No. 21-10057 (SRC)** **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. (collectively, "Bausch") and Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc., (collectively, "MSN.") This case arises from Hatch-Waxman litigation regarding patents related to the branded drug Trulance®, with active ingredient plecanatide. MSN is a pharmaceutical company which has filed ANDA No. 215780 to produce a generic version of this product. Bausch owns U.S. Patent No. 10,011,637 ("the '637 patent."). The parties seek claim construction of four terms in this patent.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared

to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms

> idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

A. The "RRT" parenthetical terms

The parties contend that they dispute the meaning of two similar phrases in claims 1 and 13:

> 1. A purified peptide comprising the GCC agonist amino acid sequence of SEQ ID NO: 1, wherein the purified peptide has the following characteristics:
> a) has a bulk density of not greater than 0.1 g/mL;
> b) contains less than 50 ppm acetamide;
> c) less than 0.25% **alpha-Asp-9-plecanatide (RRT 1.33)** per total weight of peptide; and
> d) less than 0.05% trifluoroacetic acid (TFA) per total weight of peptide.
>
> 13. The purified peptide of claim 1, wherein the peptide further contains **iso-Asp2-plecanatide (RTT 0.96-0.97)** at less than 2% of the total weight of the peptide.

The parties agree that claim 13 contains a typo in "RTT," which should be, "RRT," as it is the acronym for "Relative Retention Time;" this Court will address the meaning of the phrase as corrected by the parties. In the discussion that follows, the Court will say that each phrase has a "name part" and a "parenthetical part."

The parties agree on the meaning of all the letters and numbers in the two phrases. The name part of each phrase identifies a compound that is an undesirable impurity in the purified peptide, and the parenthetical part states a measurement of Relative Retention Time, to be assessed by the analytical method described in Example 8 as "UPLC Method 1." '637 patent,

col.101 l.12-col.102 l.112. The parties agree that the stated Relative Retention Time measurements reflect the measurement of the specified impurity that results from using the analytical method, UPLC Method 1. The parties agree that the name parts are limiting, but disagree about whether the parenthetical parts are claim limitations: Plaintiffs say they are not claim limitations, while Defendant contends that they are limiting.

In short, while there is substantial agreement about the meaning of most of the various elements of these phrases, Plaintiffs fail to persuade that there is a reason to conclude that the parenthetical parts are not claim limitations. As to the phrase in claim 1, Plaintiffs state:

> To a person of ordinary skill in the art, therefore, it would have been clear that alpha-Asp-9-plecanatide was an impurity and could be referred to by its name and further characterized by its approximate relative retention time of 1.33 under the specification's described UPLC analysis.

(Pls.' Br. at 8-9.) This appears to be a good summary of both parties' understanding of the phrase at issue in claim 1. Plaintiffs do not, however, offer a persuasive reason why the name of the impurity is a claim limitation, but the further characterization of the named impurity is not a claim limitation. In stating that the named impurity is "further characterized" by the parenthetical part, Plaintiffs express the fact that the parenthetical part states an additional characteristic of the named impurity. Why would the named impurity be a requirement, but the adjacent additional characteristic – written right next to the name in the body of the claim – not be?

Plaintiffs seem to suggest that there is something about the parentheses themselves – the actual "(" and ")" typographical marks – that carries the meaning, "not a claim limitation." Plaintiffs offer two arguments in support of this point. First, Plaintiffs point out that claim 1 also contains the phrase "trifluoroacetic acid (TFA)," and argue that this is intrinsic evidence that

the term inside the parentheses is not a claim limitation. The Court is not persuaded: 1) that a POSA would believe that parentheses have only one narrowly-defined function in technical writing; and 2) that the use of parentheses in "trifluoroacetic acid (TFA)" is analogous to the use in "alpha-Asp-9-plecanatide (RRT 1.33)." "TFA" appears to be an acronym[1] of **T**ri**F**luoro**A**cetic acid; Plaintiffs do not contend that the parenthetical parts of the disputed terms are acronyms of the name part, nor even some other kind of synonym. Rather, Plaintiffs expressly state that the parenthetical part states an additional characteristic of the name part, not an acronym. The parenthetical acronym "(TFA)" in claim 1 does not evidence an analogous use of parentheses. If anything, the use of parentheses around "TFA" in claim 1 is evidence that parentheses have multiple functions.

Second, Plaintiffs cite USPTO guidelines, which are said to require that "reference characters" are enclosed within parentheses. Plaintiffs do not contend that the parenthetical parts at issue contain reference characters; the cited guidelines are irrelevant to this issue.

Plaintiffs otherwise make arguments that challenge Defendant's position and cite extrinsic evidence, but these do not offer a persuasive justification for concluding that a phrase that further characterizes a claim limitation is not a claim limitation because it is enclosed in parentheses. Plaintiffs contend unpersuasively that, if one understands the parenthetical parts to be limiting, this converts a product claim into a product-by-process claim: the impurities are not the product, however, and identification of an impurity after synthesis and purification of plecanatide is entirely different from a process for making purified plecanatide.[2]

---

[1] Plaintiffs acknowledge that it is an abbreviation; acronyms are a type of abbreviation.

[2] Plaintiffs also argue that the named impurities remain the same no matter which chromatography technique is used to assess them. This may be so, but it does not alter the fact

A key problem for Plaintiffs is that their argument that the parenthetical parts are not limiting has no basis in Federal Circuit law. There are many cases in which the Federal Circuit has considered the question of whether or not particular claim language is limiting, but Plaintiffs neither raise such cases nor the principles involved. (See, generally, Manual of Patent Examining Procedure § 2143.03.)

Lastly, MSN makes two good points in opposition. First, MSN points to the Federal Circuit's decision in Interactive: "If the claim language is clear on its face, then our consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified." Interactive Gift Express, Inc. v. CompuServe Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001). The Court finds that the claim language is clear on its face, and Plaintiffs have not even argued that the patent specifies a deviation from the clear language of the claims. Second, MSN cites Becton: "Claims must be interpreted with an eye toward giving effect to all terms in the claim." Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP, 616 F.3d 1249, 1257 (Fed. Cir. 2010). The Court agrees with MSN that Plaintiffs' proposed construction does not give effect to all terms in the claims, while MSN's proposed construction does so.

In short, this Court agrees with MSN's position: "The recited RRT terms were written by the applicant, examined and allowed by the Patent Office, and are deliberate, explicit claim limitations." (Def.'s Resp. Br. at 2.) This Court finds that Plaintiffs have failed to offer a legal

---

that it is undisputed that the patentees referenced a particular chromatography technique with particular results in the body of the claim. Plaintiffs argue that MSN seeks to import the particular technique from the specification into the claims, which overlooks the undisputed fact that the patentees wrote into the claim both a reference to that technique and a result from its use.

justification for concluding that the parenthetical parts of the claim terms at issue are non-limiting; the parenthetical parts are claim limitations, as Defendant contends.

B. "The peptide is stable . . ."

The parties dispute the meaning of a term in claim 2:

> 2. The purified peptide of claim 1, wherein **the peptide is stable at 25° C. for at least three months.**

Plaintiffs contend that this phrase should be construed to mean: "after three months at 25° C, the peptide has a purity as measured by liquid chromatography of no less than 95%." Defendant contends that this phrase should be construed to mean: "the peptide is resistant to degradation at 25° C for at least three months."

Defendant argues persuasively that Plaintiffs have conflated stability and purity. Plaintiffs' proposed construction requires a purity measurement at only one point in time, with no assessment of change over time. Plaintiffs do not explain the logical connection between stability over three months and measured purity at the end of three months: the two appear to be different things. The claim language at issue expressly requires stability over time, not purity at one endpoint.

Defendant argues persuasively that, in the context of pharmaceutical chemistry, stability has to do with resistance to degradation. Defendant points to the specification, which cites prior art processes of synthesis and purification, which produced "high levels of impurities (e.g., contaminants resulted from organic solvents used during syntheses or purification, and degradation products or topoisomers created, e.g., during purification)." '637 patent, col.3 ll.12-16. This makes clear that impurities may be contaminants resulting from solvents during synthesis, or degradation products created during purification.

As Defendant argues, therefore, Plaintiffs' construction, which requires one measure of purity at a single point in time after synthesis, may reflect both types of impurities – the contaminants that arose during synthesis as well as the degradation products that arose later. A measure of purity taken at the end of three months thus measures impurities that may have been generated at any point in time after synthesis began, without any way to distinguish the impurities that arose over the preceding three months from those that arose earlier in time. In contrast, two purity measures taken at the beginning and end of a period of time, can show the change in purity over time. Plaintiffs' proposed construction fails to reflect the elements of change over time or duration: it requires a property at the end of three months with no reference to that property at the start of the period. Defendant's construction requires that resistance to degradation occur over three months, from start to finish, which captures the concept of stability (change over duration) stated in the claim term.

The examples in the specification support Defendant's construction, rather than Plaintiffs'. In Example 5, the specification states that Table XVI "demonstrates the stability data of plecanatide." '637 patent, col.94 ll.50-51. Table XVI shows purity data over eight points in time, from 0 to 25 hours, supporting the inference that the patentees understood the stability of plecanatide to be demonstrated by measurements of purity over a time period. Similarly, in Example 8, Table XXI bears the title, "Stability of Plecanatide . . . Stored at 25° C." '637 patent, col.103 ll.30-31. Table XXI shows chromatographic plecanatide purity percentages at 0, 3 months, and 6 months. Table XXI shows that the plecanatide sample maintained 97% purity for 3 months.[3] This supports Defendant's construction, as it gives evidence of purity over

[3] In addition, as Defendant observes, Plaintiffs propose a stability standard of 95% purity after

time, and shows that the plecanatide is resistant to degradation over a span of time.

Defendant also points to these specification statements:

> In some embodiments, the GCC agonist peptides prepared by the methods of the invention are more stable than naturally occurring GCC agonists . . . . For example, the GCC agonist peptide degrades 2%, 3%, 5%, 10%, 15%, 20%, 30%, 40%, 50%, 75%, 90% or less compared to naturally occurring GCC agonists . . .

'637 patent, col.29 ll.41-58. This clearly links peptide stability to decreased degradation; resistance to degradation is the property of having decreased degradation. The intrinsic evidence supports Defendant's construction, rather than Plaintiffs'. In claim two, the phrase "the peptide is stable at 25° C. for at least three months" means "the peptide is resistant to degradation at 25° C for at least three months."

C. "Topoisomers"

The parties dispute the meaning of the term "topoisomers" in claim 12:

> 12. The purified peptide of claim 1, wherein the peptide further contains **topoisomers** at less than 2% of the total weight of the peptide.

Plaintiffs contend that construction of this term is immaterial to this litigation, but that it should be construed to mean: "topological isomers that are impurities of the specified peptide." Defendant contends that it should be construed to mean: "any of two or more isomers of a macrocyclic molecule that display the same connectivity, bond orders, and configurations, but which differ in the degree of knotting of a loop or the degree of interlocking or rings."

The parties agree that the term in claim 12 has its ordinary meaning. Given this fundamental agreement, the Court first considers the question of whether it has before it a

---

three months, but do not point to any basis in the patent for choosing the number "95." Plaintiffs' use of 95% in the proposed construction appears arbitrary.

cognizable controversy over the ordinary meaning of "topoisomers." Plaintiffs contend that construction is not needed (although they nonetheless propose a construction), citing the Federal Circuit's decision in Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999): "only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." Plaintiffs contend that construction of "topoisomers" is not material to any contention in this litigation. Defendant, in opposition, responds that construction of the term has a bearing on its contention that claim 12 is indefinite:

> To be clear, MSN's invalidity contentions plainly state that claim 12 is indefinite because a "[person of ordinary skill] cannot know what topoisomer is covered by claim 1, such that the POSA can know which topoisomers need to be excluded." Defs.' Ex. 12, 215-216. MSN requires clarity on the proper meaning of a topoisomer in order to understand which topoisomers are present "at less than 2% of the total weight of the peptide" according to claim 12.

(Def.'s Resp. Br. at 21.) That quote from Defendant's responsive brief cites Defendant's Exhibit 12, which states:

> Claim 12 of the '637 patent requires a purified plecanatide product of claim 1 which further contains topoisomers at less than 2% of the total weight of the peptide. As explained above, claim 1 is directed to a purified peptide having the amino acid sequence of SEQ ID NO: 1. But SEQ ID NO: 1 only describes a peptide in terms of its primary sequence. It in no way describes a peptide in terms of its secondary or tertiary structure, including even any specific disulfide bonds, and therefore claim 1 is not directed to any particular topoisomer of plecanatide, e.g., the more GC-C active topoisomer of plecanatide. For at least this reason, a POSA cannot know what topoisomer is covered by claim 1, such that the POSA can know which topoisomers need to be excluded. For at least this reason, claim 12 is invalid for indefiniteness.

(Larsen Dec. Ex. 12 at 216.)

Defendant has failed to persuade the Court that construction of the term "topoisomer" in claim 12 has a bearing on MSN's invalidity contention. As explained in both Exhibit 12 and footnote 4 in MSN's opening brief, Defendant's claim 12 invalidity contention turns on the

alleged failure of claim 1 to disclose sufficient structural information to identify the purified peptide and enable a POSA to distinguish that purified peptide from the topoisomers that are present at less than 2% of the weight of the purified peptide, as required by claim 12. This indefiniteness argument thus turns on the issue of the structural characteristics that differentiate the "purified peptide" of claim 1 from the "topoisomers" of claim 12. Defendant has not, however, demonstrated that: 1) a controversy exists between the parties about the nature of the structural characteristics that differentiate the "purified peptide" of claim 1 from the "topoisomers" of claim 12; 2) an ambiguity exists in the meaning of the term "topoisomers" in claim 12 that has a bearing on the resolution of this controversy, if it exists; or 3) Defendant's proposed construction of "topoisomers" meaningfully addresses that controversy or that ambiguity. To say this more simply, Defendant has not persuaded the Court that its proposed construction of "topoisomers" in claim 12 has any meaningful connection to its argument that claim 1 fails to sufficiently inform the POSA about how to differentiate the purified peptide of claim 1 from the topoisomers of claim 12.

Furthermore, Defendant states that its proposed construction is drawn from the definition of "topoisomer" in a biochemistry dictionary. The Court questions whether this is proper under Federal Circuit law. MSN asserts that the intrinsic evidence is "silent" as to the meaning of the term, and that therefore this Court should consult a dictionary. (Def.'s Br. at 19.) First, earlier on the same page, Defendant already suggested inferences to be made from the use of "topoisomers" in the specification; the intrinsic evidence is not silent.[4] Second, the Federal

[4] The absence of an explicit definition of "topoisomers" in the specification is not equivalent to silence. In Phillips, the Federal Circuit quoted Irdeto: "Even when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the

Circuit has held: "If the meaning of a claim term is clear from the intrinsic evidence, there is no reason to resort to extrinsic evidence." Grace Instrument Indus., LLC v. Chandler Instruments Co., LLC, 57 F.4th 1001, 1008 (Fed. Cir. 2023) (quoting Seabed Geosolutions (US) Inc. v. Magseis FF LLC, 8 F.4th 1285, 1287 (Fed. Cir. 2021)). MSN has not persuaded this Court that, after reviewing the intrinsic evidence, the meaning of "topoisomers" is unclear: MSN has not explained what unresolved question of meaning requires the Court to resort to extrinsic evidence.

In sum, the Court finds here two solutions in search of a problem, two proposed constructions that do not appear to spring from any material controversy over the interpretation of particular claim language. The parties agree that the term has its ordinary meaning and point to no unresolved disputes about that ordinary meaning; the ordinary meaning of the term is not in actual controversy. Pursuant to the Federal Circuit's decision in Vivid, the Court concludes that no construction of "topoisomers" is needed.[5]

meaning may be found in or ascertained by a reading of the patent documents." Phillips, 415 F.3d at 1321 (quoting Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295, 1300 (Fed. Cir. 2004)).

[5] Because no construction is needed, the Court need not reach the substance of Plaintiffs' proposed construction, but offers the following comment: even if true that the patent at issue discloses compounds which are both topoisomers and impurities in the purified peptide, it is both an error of logic and improper under Federal Circuit law to conclude that, therefore, the meaning of the claim term, "topoisomers," is limited to impurities. No one has suggested that the ordinary meaning of "topoisoimers" is limited to impurities of something.

In conclusion, the Court construes the terms at issue as follows. The "RRT" parenthetical terms are claim limitations. In claim two, the phrase "the peptide is stable at 25° C. for at least three months" means "the peptide is resistant to degradation at 25° C for at least three months." The Court discerns no controversy over the ordinary meaning of "toposiomers" that requires claim construction.

SO ORDERED.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: April 20, 2023